No. 1:17-md-02775

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

IN RE SMITH & NEPHEW BIRMINGHAM HIP RESURFACING (BHR) HIP IMPLANT PRODUCTS LIABILITY LITIGATION

THIS DOCUMENT RELATES TO
Paula Redick, et al. v. Smith & Nephew, Inc., NO. 1:17-CV-00944

DEFENDANT SMITH & NEPHEW, INC.'S REPLY MEMORANDUM IN SUPPORT OF ITS MOTION FOR SUMMARY JUDGMENT

Timothy F. Daniels
Kim E. Moore
IRWIN FRITCHIE URQUHART & MOORE LLC
400 Poydras St. #2700
New Orleans, Louisiana 70130
tdaniels@irwinllc.com
kmoore@irwinllc.com
Tel.: (504) 310-2100
Fax: (504) 310-2101

Jana D. Wozniak
Daniel A. Spira
SIDLEY AUSTIN LLP
One South Dearborn
Chicago, Illinois 60603
jwozniak@sidley.com
dspira@sidley.com
Tel.: (312) 853-7000
Fax: (312) 853-7036

Terri S. Reiskin (Bar No. 05256)
DYKEMA GOSSETT PLLC
1301 K Street NW,
Suite 1100 West
Washington, DC 20005
treiskin@dykema.com
Tel.: (202) 906-860
Fax: (855) 216-7884

Paul J. Zidlicky (Bar. No. 26148)
Jennifer J. Clark
SIDLEY AUSTIN LLP
1501 K Street, N.W.
Washington, DC 20005
pzidlicky@sidley.com
Jennifer.clark@sidley.com
Tel.: (202) 736-8000
Fax: (202) 736-8711

Counsel for Defendant Smith & Nephew, Inc.

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INTRODUCTION AND SUMMARY

As set forth in Smith & Nephew's opening Memorandum [D.E. 2516-1] ("Memorandum" or "Mem."), judgment should be entered for Smith & Nephew on Plaintiffs' remaining claims. To avoid summary judgment, Plaintiffs argue that Smith & Nephew (1) "concealed" foreign ad hoc registry data regarding BHR revision rates in females and patients receiving smaller component sizes—what Plaintiffs dub "secret data," and (2) represented that the BHR "perform[ed] better than its competitors." Pls. Opp. to Smith & Nephew's Motion for Summary Judgment [D.E. 2592] (Mar. 26, 2021) ("Opp.") at 2. These arguments do not raise any disputes of material fact that could defeat summary judgment, which should be granted to Smith & Nephew.

Legally, Plaintiffs' "concealment" of "secret data" argument is foreclosed by the Court's holding that "[a]ny claim that Smith & Nephew had a duty to 'communicate information to patients or the medical community . . . should be preempted as an attempt to impose requirements that add to or differ from federal regulations.'" Memorandum [D.E. 2501] (Mar. 1, 2021) at 14 ("*Daubert* Ruling"). Indeed, before Ms. Redick's implant surgery, the BHR's FDA-approved label warned of an increased risk of revision for females and patients receiving smaller component sizes. Further, Plaintiffs do not challenge the accuracy of any data from the Australian Registry communicated in training or marketing materials, and their expert admits that the ad hoc data (that are the linchpin of their claim) showed subpopulation revision rates for the BHR similar to and *lower* than the Australian Registry data Ms. Redick's surgeon regularly accessed and relied upon. Deposition of Mari Truman ("Truman Dep.") (Ex. A) at 211-19. As to the representation that the BHR performed "better than its competitors," Opp. 2, Plaintiffs' expert admits that "the BHR does have better outcomes than the other resurfacing devices." Deposition of Dr. Jeffrey Shapiro ("Shapiro (MDL) Dep") (Sept. 11, 2020) (Ex. B) at 273.

The balance of Plaintiffs' Opposition suffers from similar and related shortcomings. Accordingly, summary judgment should be granted to Smith & Nephew under Rule 56.

ARGUMENT

I. SUMMARY JUDGMENT SHOULD BE GRANTED TO SMITH & NEPHEW ON PLAINTIFFS' NEGLIGENCE CLAIMS.

A. Summary Judgment Should Be Granted on the Failure to Warn Claim.

1. Federal Preemption.

Notwithstanding the Court's preemption and *Daubert* rulings, Plaintiffs insist that Smith & Nephew is liable for failure to warn Dr. Bowling "even if [it] 'may have fully complied with all Federal laws in its marketing and labeling.'" Opp. 8. They argue that Smith & Nephew failed to warn Dr. Bowling by "failing to make public the secret trend analysis showing women and patients with smaller device sizes had a higher revision risk than publicly known." *Id*. at 7. These arguments fail because "[a]ny claim that Smith & Nephew had a duty to warn the general public or the medical community" is "expressly preempted." *In re BHR*, 300 F. Supp. 3d 732, 745 (D. Md. 2018); *Daubert* Ruling at 14 ("[A]ny claim that Smith & Nephew had a duty to 'communicate information to patients or the medical community . . . should be preempted"). The cases Plaintiffs cite are inapposite as they involve non-PMA approved devices, and thus did not involve express preemption. *E.g.*, *In re DePuy Orthopaedics, Inc., Pinnacle Hip Implant Prod. Liab. Litig.,* 888 F.3d 753, 770-71 (5th Cir. 2018) (implant "brought to market through the 510(k) process").[1]

Because this claim is preempted, Plaintiffs' speculation regarding what Dr. Bowling would have done with additional data is irrelevant. Opp. 9. In any event, the suggestion that Dr. Bowling "believed the publicly available revision rates in the British and Australian Registry reflected the

[1] As a result, Plaintiffs' discussion of a duty to warn doctors under North Carolina law is irrelevant. Opp. 7-9. Smith & Nephew addresses Plaintiffs' separate argument that it "disseminat[ed] extra-labeling information about the BHR's low risk of revision" in Section I.B., *infra.*

risk to all patients, regardless of gender or device size," *id.*, is not supported by the deposition pages cited by Plaintiffs and is contrary to the record. *See* Dep. of Jack Wayne Bowling ("Bowling Dep.") (Ex. C) at 171-72 (acknowledging awareness of "debate" in the medical community about "gender" "before Ms. Redick's surgery"). Indeed, the FDA-approved label warned of higher revision risks for females and patients with smaller head sizes. Ex. D at SN_BHR_MDL0032348.

Plaintiffs also assert that Dr. Bowling "shared . . . global revision risk data with Ms. Redick, and, if he had Smith & Nephew's secret data, would have shared it with her instead." Opp. 9. But the ad hoc registry data showed similar and even *lower* revision rates for the BHR in females and patients with smaller head sizes than the registry data Dr. Bowling accessed and shared with patients. *See* Truman Dep. (Ex. A) at 211-19. That fact is fatal to this line of argument.

2. Failure to Warn the FDA.

Plaintiffs next argue that North Carolina law "*does* contemplate holding Smith & Nephew accountable for failing to warn . . . the FDA." Opp. 9. As Smith & Nephew has shown previously, *McNeil-Williams v. DePuy Orthopaedics, Inc.*, 384 F. Supp. 3d 570, 575-76 (E.D.N.C. 2019), squarely held that "North Carolina law does not recognize a parallel duty on manufacturers to report to the FDA," but instead "recognizes a duty to warn *only* users or medical practitioners in certain circumstances." 384 F. Supp. 3d at 575-76 (emphasis added). *McNeil-Williams* (i) evaluated North Carolina Gen. Stat. § 99B-5(a) (and the North Carolina Supreme Court's application of that law), (ii) conducted an independent review of North Carolina case law and (iii) held that North Carolina law does not recognize a duty to warn the FDA. *Id.*[2]

[2] Plaintiffs offer no response to the Fourth Circuit's command that, in a diversity case, "[a] federal court . . . should respond conservatively when asked to discern governing principles of state law. . . [and thus] should not interpret state law in a manner that . . . has not been approved by the state whose law is at issue." *McKiver v. Murphy-Brown, LLC*, 980 F.3d 937, 963-64 (4th Cir. 2020).

Plaintiffs' cases do nothing to undermine this result. Plaintiffs' cite *Burrell v. Bayer Corp*., 260 F. Supp. 3d 485, 492 (W.D.N.C. 2017), Opp. 10 & n.1, but that case dismissed a failure to warn the FDA claim because "the source of this continuing duty [to warn the FDA] was *federal* law," and thus the claim was preempted under *Buckman*. 260 F. Supp. 3d at 492 (emphasis added). Plaintiffs assert that the court "found the plaintiff's claim failed on causation," Opp. 10, but the court addressed causation only in the alternative. Further, *Burrell* was vacated by the Fourth Circuit for lack of subject matter jurisdiction. *See Burrell v. Bayer Corp.,* 918 F.3d 372 (4th Cir. 2019). Plaintiffs' reliance on *Holley v. Burroughs Wellcome Co*., 74 N.C. App. 736 (1985), is likewise misplaced. Opp. 10. *Holley* merely recognized that the nurse anesthetist who was "left in charge" of the plaintiff's anesthesia was a foreseeable *user* of the defendant's products to whom the duty to warn applied. *Holley*, 74 N.C. App. at 746. That case says nothing about whether there is a duty to warn the FDA—an institution that is not a user of the BHR.[3]

3. Proximate Causation.

Because Plaintiffs' failure to warn claims are preempted and not supported by North Carolina law, their discussion of proximate cause is beside the point. Further, Plaintiffs are wrong that Smith & Nephew has the burden to show that if the ad hoc data "had been submitted to the FDA and made public, it would not have reached Dr. Bowling." Opp. 11, 14. *Plaintiffs* have the burden of proving "that if the defendant had properly reported the adverse events to the FDA as required under federal law, that information would have reached her doctors in time to prevent her injuries." *Daubert* Ruling at 14 n.3. They have not met this burden.

[3] *Ziglar v. E. I. Du Pont de Nemours & Co*., 53 N.C. App. 147 (1981) is further afield. That court denied summary judgment because "plaintiff's allegations regarding the inadequacy of Du Pont's warnings raised factual issues." *Id.* at 157. Plaintiffs argue this case requires "'greater steps' than just the warning label itself," Opp. 10-11, but the "greater steps" noted were "using more prominent written warnings and symbols on the product's label." *Ziglar*, 53 N.C. App. at 157.

Plaintiffs' theory of causation requires as a first step that ad hoc data submitted to FDA by Smith & Nephew would be made public. Opp. 11-12 (describing the causal chain as "if Smith & Nephew's [ad hoc data] had been submitted to the FDA *and made public*") (emphasis added). But Plaintiffs have disavowed any argument about what FDA would have done if it received different information. *See Daubert* Ruling at 23 ("[P]laintiffs, appropriately, do not plan to offer speculative testimony about what the FDA might or might not have done if presented with different or additional information").[4] Further, the BHR ad hoc Australian Registry data upon which Plaintiffs' claim depends showed similar and even *lower* incidences of revision in females and small component sizes than Registry data regarding resurfacings available and regularly accessed by Dr. Bowling. *See* Truman Dep. (Ex. A) at 211-19 (Plaintiffs' expert comparing (i) revision rates in 2010 ad hoc registry reports regarding the BHR, with (ii) publicly available 2010 registry data provided to FDA regarding resurfacing procedures and conceding that "in each case the BHR is performing better").[5] Plaintiffs cannot show that if Smith & Nephew had submitted ad hoc data to the FDA, it would have made any difference to Ms. Redick.[6]

[4] Plaintiffs' passing reference that Dr. Bowling would not have implanted the BHR in Ms. Redick "if the BHR had been contraindicated," Opp. 14, is likewise foreclosed for this same reason.

[5] Because Smith & Nephew did not have a duty to warn Ms. Redick or Dr. Bowling, causation cannot be based on Smith & Nephew failing to provide ad hoc registry data in public statements. Opp. 12 (speculating that the data could have been "made public" through "voluntary, extra-labeling statements"); *id.* at 15 ("to the extent Ms. Redick read Smith & Nephew materials").

[6] Plaintiffs also point to a statement by Smith & Nephew's CEO to investors, Opp. 13, but submit no evidence that Ms. Redick or Dr. Bowling ever saw or relied on that statement. In any event, that statement about "survival" pertains to patient mortality (*i.e.*, deaths) not revision rates, and the statement accurately reflects NJR data. *See* Ex. E at SN_BHR_MDL_3477516 (referring to "mortality rates" from NJR data presented at "BOA" meeting, which Smith & Nephew's CEO would like to use "for his quarterly results call"); Ex. F at SN_BHR_MDL0489362 (underlying mortality data cited by Smith & Nephew CEO, reflecting 98.5% "survival" for the BHR).

B. Summary Judgment Should Be Granted on Negligent Misrepresentation.

Although North Carolina law requires that negligent misrepresentation claims "be stated with particularity," Mem. 18, Plaintiffs have failed to do so, *id.* at 18-22. Instead, they argue that "Ms. Redick personally viewed information about the BHR that included the *key misrepresentation*, the global Australian and British Registry revision risk that was misleading as to the revision risk specific to her, both in the form of written materials and the Australian and British Registry results that Dr. Bowling personally shared with her." Opp. 15 (emphasis added) (citing Ex. 7 at 114; Ex. 14). They appear to be arguing that "Smith & Nephew concealed internal secret data showing a higher risk of revision in women and patients with smaller femoral head sizes." *Id.* at 2. This argument does not support a claim of negligent misrepresentation.[7]

First, Smith & Nephew cannot be liable for the information contained in the Australian Registry or UK Registry that Dr. Bowling allegedly shared with Ms. Redick. A negligent misrepresentation is a statement "prepared without reasonable care by one who owed the relying party a duty of care." *Raritan River Steel Co. v. Cherry, Bekaert & Holland*, 367 S.E. 2d 609,

[7] Plaintiffs attempt to divert attention from this failure of proof by arguing that Ms. Redick can rely upon statements that Smith & Nephew allegedly made to her physician, Dr. Bowling that he in turn conveyed to Ms. Redick. Opp. 16-19 (citing *Rowan Cty. Bd. of Educ. v. United States Gypsum Co.*, 332 N.C. 1 20-22 (N.C. 1992)). That argument fails for multiple reasons. First, North Carolina requires that any negligent misrepresentation be made "directly" to Ms. Redick. *See Hospira Inc. v. Alphagary Corp.*, 671 S.E.2d 7, 12 (N.C. App. 2009). Unlike *Rowan*, where the statements in question were made to a third party acting as an agent of the principal, here there has been no showing that Dr. Bowling was Ms. Redick's "agent" when any statements allegedly were made to him. *Cf. Hospira*, 671 S.E. 2d at 11 (explaining that *Rowan* "give[s] the term 'agent' … "its legal meaning," requiring "(1) the authority of the agent to act on behalf of the principal, and (2) the principal's control over the agent"). Further, Dr. Bowling testified he does not believe that Smith & Nephew ever made any misrepresentation to him. *See* Mem. 20 & Bowling Dep. [D.E. 2516-6] at 194-95. And, Ms. Redick did not recall Dr. Bowling sharing any information with her about the BHR's risks, including any revision rates from the Australian and UK registries, or even that the BHR was made of metal. Mem. at 9, 20.

612 (N.C. 1988). Smith & Nephew did not prepare the Australian or UK Registry data that Dr. Bowling testified he regularly reviewed. *See* Bowling Dep. (Ex. C) at 60-62.

In fact, Plaintiffs do not contend that the public Australian Registry data support a misrepresentation claim. Rather, their claim is that Smith & Nephew should be held liable for failing to share *additional* information—i.e., the BHR ad hoc data—concerning "a higher risk of revision in women and patients with smaller femoral head sizes." Opp. 2. That claim of concealment is baseless. It ignores that the BHR's FDA-approved labeling at the time specifically warned that patients who were female or who had smaller component sizes had a higher risk of revision. Under "**WARNINGS AND PRECAUTIONS**," the label stated:

> [T]he following were identified as risk factors for revision: *Patients who are female; who receive a smaller component size (≤44mm)*; have the device implanted at a high abduction angle; are obese; or, who have a diagnosis of avascular necrosis *have a greater risk of revision than other patients*. *The more risk factors a patient has, the greater the risk of procedure failure requiring a revision to the hip*.

Ex. D at SN_BHR_MDL0032348 (emphasis added). Moreover, the linchpin of Plaintiffs' argument—the BHR ad hoc Registry data—showed similar or *lower* revision rates for the BHR in females and patients receiving smaller device sizes than the Registry Annual Report data that Dr. Bowling regularly accessed. As Plaintiffs' expert, Mari Truman, conceded, "if we look at the revisions per hundred observed years, it is better in the BHR. . . . And then if we look at the cumulative percent, it is also better, but similar. . . . ***[I]n each case the BHR is performing better. It's a similar trend, but better***." Truman Dep. (Ex. A) at 211-19 (emphasis added); *id*. (comparing (i) revision rates in 2010 ad hoc registry report regarding the BHR, with (ii) publicly available 2010 registry data provided to FDA regarding resurfacing procedures).

Contrary to Plaintiffs' argument, the "Graves Letter" does not suggest that the BHR "perform[ed] the same as the publicly available data for all resurfacing devices . . . ." Opp. 4 (citing Ex. 5). The Graves Letter merely (i) "confirms" that a Smith & Nephew presentation to

surgeons was *consistent* with ad hoc data in the 2010 Annual Report, which Smith & Nephew was free to use in surgeon training; and (ii) *declines* Smith & Nephew's request to share ad hoc data with surgeons—*precisely what Plaintiffs argue Smith & Nephew was required to do*. *See* Ex. 5 to Opp. That Smith & Nephew was given permission to represent that the BHR "performs in a similar manner" refers to the fact that the Registry includes data on "all resurfacing procedures" (*id*.) but that Smith & Nephew could say that overall "the BHR performs in a similar manner. *Id.* It does not represent a conclusion that the BHR has "the same" subpopulation revision rates as competitors, Opp. 4, nor does it refute Plaintiffs' expert's concession that, based on this data, "the BHR is performing better." Truman Dep. (Ex. A) at 211-19.[8]

Further, Plaintiffs' negligent misrepresentation claim fails under federal and state law. Plaintiffs contend that Smith & Nephew failed to share ***additional data*** with Dr. Bowling or Ms. Redick. But Smith & Nephew had no duty to share information with the medical community or with patients, and any state-law claim predicated on a failure to provide such information is preempted. *In re BHR I*, 300 F. Supp. 3d at 745; *Daubert* Ruling at 4, 14. Indeed, North Carolina law does not recognize a claim for negligent misrepresentation based upon omissions. *See* Mem. 21-22. Plaintiffs offer no response to this precedent that forecloses their claim that Smith & Nephew "concealed internal secret data."[9]

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[8] Plaintiffs imply that Smith & Nephew made an affirmative representation that the registry data Smith & Nephew cited "applied to all BHR patients." Opp. 21. But Plaintiffs have never identified an instance of Smith & Nephew making such an assertion. Additionally, whatever understanding Dr. Bowling had about the BHR does not mean that Smith & Nephew was the source of that understanding, as Dr. Bowling obtained information about the BHR from a variety of sources, including "just kind of staying abreast of the information that you hear through your colleagues and . . . your contacts." Bowling Dep. [D.E. 2516-6] at 53-54.

[9] *Christiansen v. Wright Med. Tech., Inc.*, 127 F. Supp. 3d 1306, 1363 (N.D. Ga. 2015), does not support Plaintiffs argument that "any wrongful concealment or nondisclosure of material information" from Dr. Bowling can support their negligent misrepresentation claim. Opp. 18. Unlike the device at issue in *Christiansen*, the BHR received pre-market approval that preempts

Second, for similar reasons, the patient brochure (Ex. 14 [D.E. 2592-15] to Opp.) does not support a negligent misrepresentation claim. Plaintiff herself testified that she did not rely upon any patient brochure in deciding to have the BHR implant. Mem. 30 (confirming that Ms. Redick did not decide on the BHR based upon "any advertising" or "other written material or anything else"). And Plaintiffs make no showing that Dr. Bowling relied upon a patient brochure to recommend the BHR to Ms. Redick. Accordingly, the patient brochure (Ex. 14 to Opp.) is irrelevant to this case.

Further, the brochure makes no misrepresentations, and certainly no negligent misrepresentations. It states that the BHR's "rate of survivorship is comparable to standard total hip replacements after five years." *Id.* Specifically, the brochure states:

- 2009 Australian Registry's results showed BHR Hip's survivorship at 8 years (95%) is better than all other resurfacing implants' survivorship after just the 5th year.
- 2008 Australian Registry's study found that resurfacing devices outperformed total hip replacement for men under age 55, as well as ages 55-64.
- Great Britain's Oswestry Outcomes Centre's patient registry revealed BHR Hip's 10-year survivorship of 95.4%, with 98.6% of patients rating their opinion of the experience as 'pleased' or extremely pleased.

Id. at SN_BHR_MDL_0076420. Each statement cross-references an independent source, *id.*, and Plaintiffs do not and cannot dispute that the independent sources support these statements.

Finally, Plaintiffs also argue that Smith & Nephew stated "the BHR's use of as-cast metal performed better than competing devices that used heat-treated metal." Opp. 21 (citing Exs. 1-4 [D.E. 2592-2 through 5]). But there is no evidence that Dr. Bowling made his treatment recommendations based on the purported reasons *why* the BHR performed better than competing devices. He believed (and still believes) the BHR performed better, Bowling Dep. (Ex. C) at 228,

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any claim based upon a failure to provide information to patients or physicians, and, as discussed above, North Carolina does not recognize negligent misrepresentation based upon an omission.

and the available data showed that this was true. Dr. Bowling recommended the BHR for Ms. Redick not because it was as-cast, but because (i) a hip resurfacing device (rather than a total hip arthroplasty) would allow Ms. Redick to return to an active lifestyle and (ii) the BHR was "the best resurfacing device available at the time." *Id.*[10]

Notwithstanding their protests, Opp. 5, Dr. Bowling's view is shared by Plaintiffs' own expert, Dr. Shapiro. Plaintiffs acknowledge that Dr. Shapiro testified that the BHR's "numbers that were presented were better than their competitors," *id*., but argue that he meant to say that the numbers only *looked* better because "Smith & Nephew presented 'numbers' that masked the revision rates among subpopulations," *id.* That is wrong. Dr. Shapiro twice testified the BHR performs better than other resurfacing competitors, based on his own research:

> Q. I think we talked earlier about a document saying that the BHR was better than other resurfacings. ***It is your opinion from your research that the BHR does have better outcomes than the other resurfacing systems, correct***?
>
> A. [Dr. Shapiro]. ***That's my understanding, yes***.

Shapiro Dep. (Ex. B) at 273 (emphasis added). Thereafter, in connection with Ms. Redick's case, Dr. Shapiro testified that the BHR performed better than its hip resurfacing competitors:

> Q. Okay. All right. Final question. Do you agree that at the time of Ms. Redick's 2012 BHR surgery, that the BHR was the highest performing resurfacing device on the market?

[10] The advantages of "as-cast" designs over "heat-treated" designs are amply supported by extensive scientific research and analysis. *See*, *e.g*., J. Daniel, *et al*., Ten-year results of double-heat treated metal-on-metal hip resurfacing, *The Journal of Bone & Joint Surgery*, 92B(1), at 25 (2010) (Ex. G) ("Evidence has now emerged from physiologically-relevant hip-simulator tests that under these realistic test protocols heat-treated devices have shown significantly higher wear compared with as-cast devices"); Kamali A, et al. Tribological performance of various CoCr microstructures in metal-on-metal bearings: the development of a more physiological protocol in vitro, *The Journal of Bone & Joint Surgery*, at 724 (May 2010) (Ex. H) ("Both gravimetric and metal ion measurements showed that double-heat-treated CoCrMo hip resurfacing devices had a significantly higher wear rate than as-cast CoCrMo devices.").

A. Relative to what? Relative to what?

Q. Other resurfacing devices. Other resurfacing devices.

A. Other resurfacing devices. Okay. So to the best of my understanding, they were -- what I would like to describe is they were maybe the best of the worst. Let's put it that way.

Q. So is the answer to my question, was it the best performing of the 16 resurfacing devices? Yes or no?

A. Their numbers that were presented were better than their competitors.

Ex. K to Mem. [D.E. 2516-13] at 320.

Summary judgment should be granted to Smith & Nephew on negligent misrepresentation.

C. Summary Judgment Should Be Granted on the Surgeon Training Claim.

Plaintiffs' failure to train claim fails because (1) Plaintiffs seek to impose requirements different from or in addition to FDA's training requirements, and (2) Dr. Bowling indisputably "did a good job" implanting Ms. Redick's BHR, so that the purported learning curve for implanting the BHR did not "play[] a part" in this case. Mem. 22-26.

Plaintiffs concede that a negligent training "'claim survives preemption only to the extent that the manufacturer failed to provide the training required by the MDA.'" Opp. 22 (quoting *Burrell*, 260 F. Supp. 3d at 493). As in *Burrell*, Plaintiffs have not shown that Smith & Nephew "failed to provide the training required by the MDA." *Id*. They do not dispute that "FDA did not provide specific requirements for the content of the surgeon training program," or that there was no duty to modify or update the surgeon training program. Mem. 23, 25. Against this backdrop, none of Plaintiffs' arguments supports a viable failure to train claim.

First, Plaintiffs argue that "Ms. Redick's negligence claims arise from statements outside the FDA-approved BHR labeling about the revision risk of the BHR that were made during training." Opp. 22; *see also id.* ("Ms. Redick's negligent failure to warn and negligent

misrepresentation claims that arise from statements during training that were not truthful, were misleading, or that included warnings not included in the labeling meet this test."). Plaintiffs do not, because they cannot, challenge the accuracy of information provided to Dr. Bowling—during training or elsewhere—about "the revision risk of the BHR." *Id*. at 22. Here, too, their argument is that Smith & Nephew failed to provide *additional* information—included in foreign ad hoc Registry reports—about the revision risk of the BHR in female patients and those receiving smaller component sizes. *See, e.g., id*. 9 (arguing that Smith & Nephew provided Dr. Bowling with "global revision risk data" contained in the British and Australian Registry at "FDA-required training," but did not provide purportedly "secret data").

This argument runs headlong into (i) Plaintiffs' own concession that "FDA did not provide specific requirements for the content of the surgeon training program," Pls.' Resp. to Smith & Nephew's Motions to Exclude Expert Opinions [D.E. 2427] at 86, (ii) the Court's conclusion that "the FDA did not initially provide any other specific requirements for the content of the surgeon training program," *Daubert* Ruling at 5, and (iii) the Court's holding that "[a]ny claim . . . that Smith & Nephew had a duty to . . . communicate information to patients or the medical community" constitutes "an attempt to impose requirements that add to or differ from federal regulations." *In re BHR*, 300 F. Supp. 3d at 745. Thus, any argument that Smith & Nephew should have provided additional revision rate information during surgeon training is preempted. *See* Mem. 23-25.

Further, Plaintiffs' argument that Smith & Nephew failed to communicate supposedly "secret" data cannot support a failure to train claim for the additional reason that Smith & Nephew did not receive the foreign ad hoc registry data that Plaintiffs rely upon until years ***after*** Dr.

Bowling's 2006 training.[11] That fact is dispositive because "no requirement to make updates to that program has been identified." *Daubert* Ruling at 15 (holding that a claim that Smith & Nephew had a "duty to modify its training program" is preempted).

Finally, Plaintiffs argue that a 2015 YouTube video in which Mr. McMinn purportedly points to a "'learning curve' of 500 - 1,000 surgeries" remains relevant to their claim that Dr. Bowling was not adequately trained years earlier. Opp. 22. Plaintiffs argue that this video is relevant, because Mr. McMinn's statement pertains to a review of his earlier-available data and the ability to "replicate his results," not the ability to "technically perform the surgery." *Id*. at 23 (emphasis omitted). As noted, and as Plaintiffs have conceded, FDA did not impose requirements regarding the content of surgeon training, and FDA certainly did not require that Smith & Nephew inform surgeons of a "500-1,000 patient" learning curve, a number that Dr. Bowling and Plaintiffs' expert agree is "excessive" and "absurd." Mem. 22-23. Any state law claim premised on a requirement that Smith & Nephew provide this information in surgeon training would impose requirements different from or in addition to federal law, and is preempted. *Id.* at 23-24.[12]

Plaintiffs also argue that although Mr. McMinn's statement was made in 2015, many years after Dr. Bowling was trained, it remains relevant because Mr. McMinn was purportedly

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[11] *See* Pls.' Resp. to Smith & Nephew's Motions to Exclude Expert Opinions [D.E. 2427] at 30 ("***As early as 2009***, Smith & Nephew began regularly requesting unpublished, non-public ad hoc reports showing differences in revision rates in subpopulations") (emphasis added); Opp. 4 (citing Pls.' Resp. to Smith & Nephew's Motions to Exclude Expert Opinions for the assertion that Smith & Nephew obtained "secret, unpublished data").

[12] Plaintiffs also cannot support their theory that Mr. McMinn's statements render Smith & Nephew's purported representations about "comparative design advantages" and "low revision rates" false or misleading. Opp. 24. The BHR indisputably *is* designed differently than other devices, and Plaintiffs do not challenge the accuracy of revision rate data regarding the BHR that they agree were "evidenced by the Australian and British Registries." *Id.* at 5; *see also id*. at 9 (acknowledging that low BHR revision rates were "shown in the Australian and British Registries"); Smith & Nephew's Mem. in Opp. to Redick's Motion for Summary Judgment [D.E. 2593] at 3-6 (addressing representations allegedly made to Dr. Bowling regarding revision rates).

"analyzing surgeries from the 1990s and early 2000s, meaning his survivorship data was available well before Ms. Redick's 2012 surgery." Opp. 23. But even if the implant surgeries relevant to his analysis were performed in "the 1990s and 2000s," it does not follow that Mr. McMinn's purported *conclusion* was "available [to Smith & Nephew] . . . before Ms. Redick's 2012 surgery," let alone before Dr. Bowling's training, conducted with Mr. McMinn in 2006. *Id.*[13] In any event, Plaintiffs do not attempt to address or dispute that their own expert agreed that the purported "learning curve" does not "play[] a part" in this case. Mem. 24 (quoting Shapiro Dep. [D.E. 2516-13] at 232-33).

Summary judgment should be granted on the failure-to-train claim.

D. Summary Judgment Should Be Granted on the Negligence Per Se Claim.

Plaintiffs base their negligence per se claim on (1) North Carolina's misbranding statute, (2) a North Carolina criminal law prohibiting false or misleading advertising "done willfully and with intent to mislead," N.C. Gen. Stat. 14-117, and (3) "violations of federal requirements to inform FDA and make public its trend analysis." Opp. 25-26. Each of these falls short.

This Court has held that any claim challenging the FDA-approved label is preempted. *Daubert* Ruling at 10-12. Plaintiffs contend that North Carolina's misbranding statute covers statements made outside of the product's label. Opp. 25. That is wrong. Under North Carolina law, a device is deemed to be misbranded if "its *labeling* is false or misleading in any particular." N.C. Gen. State § 106-134(1) (emphasis added). And it defines "labeling" as "all labels and other written, printed, or graphic matter a. *Upon an article or any of its containers or wrappers*, or b.

[13] Likewise, Plaintiffs' argument that "Dr. Marc Hungerford testified that literature or information published after a plaintiff's surgery is relevant to the informed consent discussion" does not support their claim. *Id*. at 22-23. What Dr. Hungerford stated—in a case-specific opinion for a *different* plaintiff's case—was that data contained in published articles could be, in certain circumstances, available in different forms earlier. Deposition of Dr. Marc Hungerford (Sedgwick) (Ex. I) at 12-13. That testimony has nothing to do with Plaintiffs' failure to train claim.

Accompanying such article." N.C. Gen. Stat. Ann. § 106-121(11) (emphasis added). Indeed, the definition of "advertisement" expressly *excludes* "labeling," defining it as "all representations disseminated in any manner or by any means, *other than by labeling.*" N.C. Gen. Stat. Ann. § 106-121(1) (emphasis added). Plaintiffs' misbranding claim would call into question FDA-approved labeling and is thus preempted. *Daubert* Ruling at 10-12.

Plaintiffs next rely on North Carolina's criminal false advertising provision. Negligence per se requires a showing that defendant violated the provision at issue. Plaintiffs have offered no evidence whatsoever to show that Smith & Nephew violated this criminal law, including, the mens rea requirement that the false advertisement be "done willfully and with intent to mislead," N.C. Gen. Stat. § 14-117. In any event, any claim based on alleged false advertising fails for the same reasons as Plaintiffs' negligent misrepresentation claims as explained in Section I.B., *supra.*

Finally, Plaintiffs rely on supposed federal requirements for Smith & Nephew "to inform FDA and make public its trend analysis." Opp. 26. As this Court has repeatedly held, there is no federal requirement to provide information to the public. And any claim based on a requirement to inform the FDA fails for the reasons stated in Section I.A., *supra.*[14]

II. SUMMARY JUDGMENT SHOULD BE GRANTED TO SMITH & NEPHEW ON PLAINTIFFS' BREACH OF EXPRESS WARRANTY CLAIM.

Plaintiffs have failed to identify any express warranties that were the cause of any of Ms. Redick's injuries. Mem. 29-31. They have abandoned any argument that Smith & Nephew made any express warranty to Ms. Redick and instead argue only that Smith & Nephew made "specific promises and affirmations . . . to Dr. Bowling . . . regarding the magnitude of risks of revision for

[14] And, *Stoddard v. Pliva USA, Inc*., No. 4:08-CV-173-H, 2013 WL 9675385, at *3 (E.D.N.C. Nov. 21, 2013) does not present "exactly the situation here." Opp. 27. Unlike *Stoddard*, Plaintiffs have disavowed any reliance on any action that FDA would have taken had it received other data.

the BHR" that they argue "were the reason both Dr. Bowling recommended [the] BHR and Ms. Redick elected to move forward with that particular device." Opp. 31. They contend that "[t]he true failure rates of [the] BHR were not shared with Dr. Bowling, and the BHR 'did not live up to Defendant's representations.'" *Id.* These arguments fail as a matter of fact and law.[15]

First, to establish a breach of express warranty, Plaintiffs must identify "specific words, promises, affirmations, or statements made by [the defendant] to Plaintiff . . . that would create an express warranty." Mem. 29; *see also Hospira*, 2011 WL 3439145, at *6 (dismissing express warranty claim where Plaintiff failed to identify "how the warranty was made, to whom it was made, or any other details with regard to the alleged warranty"). Here, Plaintiffs do not identify any "specific words, promises, affirmations, or statements" by Smith & Nephew that "did not live up to Defendant's representations." Opp. 30. They offer no evidence that any representations made by Smith & Nephew to Ms. Redick or Dr. Bowling "regarding the magnitude of risks of revisions for the BHR" were inaccurate, were not based upon accurate data, and "did not live up to [Smith & Nephew's] representations." *Id*. at 31. Nor do Plaintiffs identify specific guarantees or promises by Smith & Nephew concerning how long the BHR would last or how it would perform in Ms. Redick. *See* Deposition of Dr. Jeffrey Shapiro (Jan. 26, 2021) (Ex. J) at 129 (agreeing that "no surgeon can guarantee" how long a "hip implant can last"); *id*. at 133 ("We

[15] None of the cases cited by Plaintiffs undercuts Smith & Nephew's showing. Those cases involve motions to dismiss breach of warranty claims and thus assess whether the factual allegations—taken as true—were sufficient to allow the claim to proceed to discovery. *See City of High Point v. Suez Treatment Sos., Inc.*, 485 F. Supp. 3d 608, 628 (M.D.N.C. 2020) (dismissing breach of express warranty claim where plaintiff failed to allege that defendant made warranties to plaintiff); *McCauley v. Hospira, Inc.*, No. 1:11-cv-108, 2011 WL 3439145, at *6 (M.D.N.C. Aug. 5, 2011) (dismissing express warranty claim where "Plaintiff does not further address the alleged express warranty or its contents and does not address at all how the warranty was made, to whom it was made, or any other details with regard to the alleged warranty"); *McDonald Bros., Inc. v. Tinder Wholesale, LLC*, 395 F. Supp. 2d 255, 267 (M.D.N.C. 2005) (denying motion to dismiss).

[surgeons] don't make guarantees"). Indeed, Dr. Bowling testified that he would convey no such guaranties to his patients. Bowling Dep. [D.E. 2516-6] at 224 ("I can't guarantee success outcomes because they're outside of my control").

Second, Plaintiffs' actual argument is based upon a duty to provide additional information. They argue that "true failure rates of [the] BHR were not shared with Dr. Bowling," Opp. 31, and contend that Smith & Nephew failed to supply additional data concerning "revision rates among subpopulations," *id.* at 5. Once again, that argument fails as a matter of law because "any claim that Smith & Nephew had a duty to 'communicate information to patients or the medical community . . . should be preempted as an attempt to impose requirements that add to or differ from federal regulations.'" *Daubert* Ruling at 14 (quoting *In re BHR*, 300 F. Supp. 3d at 745). Indeed, unlike an implied warranty, a breach of express warranty claim requires an "express warranty as to a fact or promise relating to the goods." *City of High Point,* 485 F. Supp. 3d at 628.

Third, before Ms. Redick's surgery, Smith & Nephew did, in fact, share, through its FDA-approved label, that risk factors for revision for the BHR include: (1) "[p]atients who are female" and (2) patients "who receive a smaller component size (≤44mm)," and (3) that "[t]he more risk factors a patient has, the greater the risk of procedure failure requiring a revision to the hip." Ex. D at SN_BHR_MDL0032348. Further, data regarding the risk of revision for females and for patients with small head sizes were available in the Australian Registry, which Dr. Bowling testified he reviewed and shared with his patients, including Ms. Redick. Bowling Dep. (Ex. C) at 62 ("I would look at the Australian Registry data"); *id.* at 106 ("Q. Did you share Australian Registry results with patients directly? A. Yes.").

Finally, Plaintiffs argue that Smith & Nephew failed to share ad hoc Australian Registry data with Dr. Bowling. Opp. 9. As noted, any claim that Smith & Nephew was required to provide

information to Dr. Bowling is preempted, but, even if it were not, the ad hoc Registry data could make no difference. As noted above, Plaintiffs contend that the "Australian Registry reflected the risk to all patients, regardless of gender or device size." *Id.* That is wrong. The Australian Registry Annual Report data available before Ms. Redick's implant surgery reflected revision rates by gender and device size for resurfacings. Truman Dep. (Ex. A) at 211-19. Further, the ad hoc Registry data specific to the BHR showed similar or *lower* revision rates in females and patients receiving smaller device sizes than did the Australian Annual Report data for resurfacings. *See id*. (Plaintiffs' expert comparing (i) revision rates in 2010 ad hoc Registry report regarding the BHR, with (ii) 2010 Annual Report Registry data provided to FDA regarding resurfacing procedures).[16]

Summary judgment should be granted on Plaintiffs' breach of express warranty claim.

III. PLAINTIFFS CANNOT RECOVER PUNITIVE DAMAGES.

Plaintiffs do not dispute that if their other claims fail as a matter of law, they cannot recover punitive damages. *See* Mem. 31; Opp. 31; *Iadanza v. Harper*, 611 S.E.2d 217, 223 (N.C. App. 2005) ("If the injured party has no cause of action independent of a supposed right to recover punitive damages, then he has no cause of action at all."). For the reasons set forth above and in Smith & Nephew's opening Memorandum, each of Plaintiffs' remaining causes of action fails as a matter of law, and as a result, so too does their request for punitive damages.

Additionally, Plaintiffs' request for punitive damages should be denied because they have not presented evidence of "fraud, malice, or willful or wanton conduct." Mem. 31-34; *see* N.C.

[16] As Ms. Truman conceded, "if we look at the revisions per hundred observed years, it is better in the BHR. . . . And then if we look at the cumulative percent, it is also better, but similar. . . . [I]n each case the BHR is performing better. It's a similar trend, but better." *Id*. (emphasis added); *see id.* at 218 (Q. . . . [I]n terms of providing to FDA the true revision rate for females and small head sizes by providing the public annual report data, it's providing revision rates that are actually higher than what the ad hoc data shows for females, for head sizes, and for female and head sizes combined; correct? A. It is. . . .").

Gen. Stat. § 1D-15(a). Plaintiffs argue that they can meet that standard, and Smith & Nephew should be liable for punitive damages for "marketing a product while knowingly concealing its risks." Opp. 32. But Plaintiffs ignore Smith & Nephew's disclosure, at all times, of the BHR's "risks" through its labeling reviewed and approved by the FDA. Plaintiffs do not address how Smith & Nephew can be held liable for "concealing" risks when it indisputably included in its labeling exactly those risks that FDA required and permitted.

Plaintiffs further argue that Smith & Nephew "conceal[ed] its secret data [*i.e.*, foreign registry ad hoc reports] while sending marketing pieces touting the BHR's low revision rates . . . ." Opp. 32. Again, Plaintiffs do not, because they cannot, challenge the accuracy of any revision rate contained in any Smith & Nephew "marketing pieces" received by Dr. Bowling or Ms. Redick. Rather, they acknowledge that Smith & Nephew's "factual representations about the BHR's clinical performance" were "evidenced by the Australian and British Registries." Opp. 5; *id*. at 9 (arguing that Smith & Nephew disseminated revision rate information "***as shown in the Australian and British Registries***") (emphasis added). To the extent Plaintiffs' argument is that Smith & Nephew's marketing pieces did not volunteer *additional* subpopulation revision rate information contained in foreign ad hoc Registry reports, *see* Opp. 32, they cannot square this with (i) the Court's holding that "[a]ny claim . . . that Smith & Nephew had a duty to . . . communicate information to patients or the medical community" constitutes "an attempt to impose requirements that add to or differ from federal regulations," *In re BHR*, 300 F. Supp. 3d at 745; *accord Daubert* Ruling at 14; and (ii) the exclusion of expert evidence that "Smith & Nephew should have provided revision data 'to implanting surgeons . . . by way of . . . a Dear Doctor letter or other

communication,'" *id.* at 13-14. The argument that Smith & Nephew failed to provide ad hoc data to surgeons cannot give rise to liability or support a request for punitive damages.[17]

Summary judgment should be granted on Plaintiffs' request for punitive damages.

CONCLUSION

For these reasons, and the reasons set forth in Smith & Nephew's opening memorandum, summary judgment should be granted as to the remaining claims of Plaintiffs under Rule 56.

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Respectfully Submitted,

/s/ Paul J. Zidlicky

Timothy F. Daniels
Kim E. Moore
IRWIN FRITCHIE URQUHART & MOORE LLC
400 Poydras St. #2700
New Orleans, Louisiana 70130
tdaniels@irwinllc.com
kmoore@irwinllc.com
Tel.: (504) 310-2100
Fax: (504) 310-2101

Terri S. Reiskin (Bar No. 05256)
DYKEMA GOSSETT PLLC
1301 K Street NW, Suite 1100 West
Washington, DC 20005
treiskin@dykema.com
Tel.: (202) 906-8600
Fax: (855) 216-7884

Jana D. Wozniak
Daniel A. Spira
SIDLEY AUSTIN LLP
One South Dearborn
Chicago, Illinois 60603
jwozniak@sidley.com
dspira@sidley.com
Tel.: (312) 853-7000
Fax: (312) 853-7036

Paul J. Zidlicky
Jennifer J. Clark
SIDLEY AUSTIN LLP
1501 K Street, N.W.
Washington, DC 20005
pzidlicky@sidley.com
jennifer.clark@sidley.com
Tel.: (202) 736-8000
Fax: (202) 736-8711

Counsel for Defendant Smith & Nephew, Inc.

[17] *Rowan*, 332 N.C. 1, is inapposite. *See* Opp. 31-32. *Rowan* involved a fraud claim supported by evidence that defendant concealed the harmful effects of asbestos contained in its product, and "heavily promoted [the product] as suitable for use in schools" through "specific representations" despite knowing its lack of suitability for such locations, and as a result, "the jury's finding of fraud . . . was sufficient to support the . . . punitive damages award." 332 N.C. at 17, 22. Here, by contrast, Plaintiffs do not have a fraud claim; Plaintiffs have not identified any "specific representations" that Smith & Nephew made to Dr. Bowling or Ms. Redick that were false or misleading, let alone ones that were "reasonably calculated to deceive" and "made with intent to deceive" as required for a fraud claim, *id*. at 17; and the BHR is a Class III premarket approved medical device, the warnings for which were at all times reviewed and approved by the FDA.

CERTIFICATE OF SERVICE

I, Jana D. Wozniak, hereby certify that on this 9th day of April, 2021, I electronically filed the foregoing with the Court using the CM/ECF system, and thereby delivered the foregoing by electronic means to all counsel of record.

/s/ Jana D. Wozniak
Counsel for Defendant Smith & Nephew, Inc.